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03/15/24 • BIG PHARMA › NEWS

GSK and Pfizer RSV Vaccines for Pregnant Women Increased Risk of Preterm Births — GSK Ended Its Trials, but FDA Approved Pfizer Shots

GSK stopped developing a vaccine for pregnant women to protect newborns against syncytial virus (RSV) after identifying an increased risk of preterm births. Pfizer won approval of its nearly identical vaccine after the company said the increased rate of preterm births in its trials was statistically insignificant.

By **Brenda Baletti, Ph.D.**

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GSK on Thursday provided more details on the clinical trials for its maternal respiratory syncytial virus (RSV) vaccine. The company halted the trials and stopped developing the vaccine in February 2022, after identifying an increased risk of preterm birth among vaccinated mothers.

The details, published in a peer-reviewed article in the New England Journal of Medicine (NEJM), came after GSK previously reported the increased risk and subsequent termination of the trials to regulators, GSK's investors and in the press.

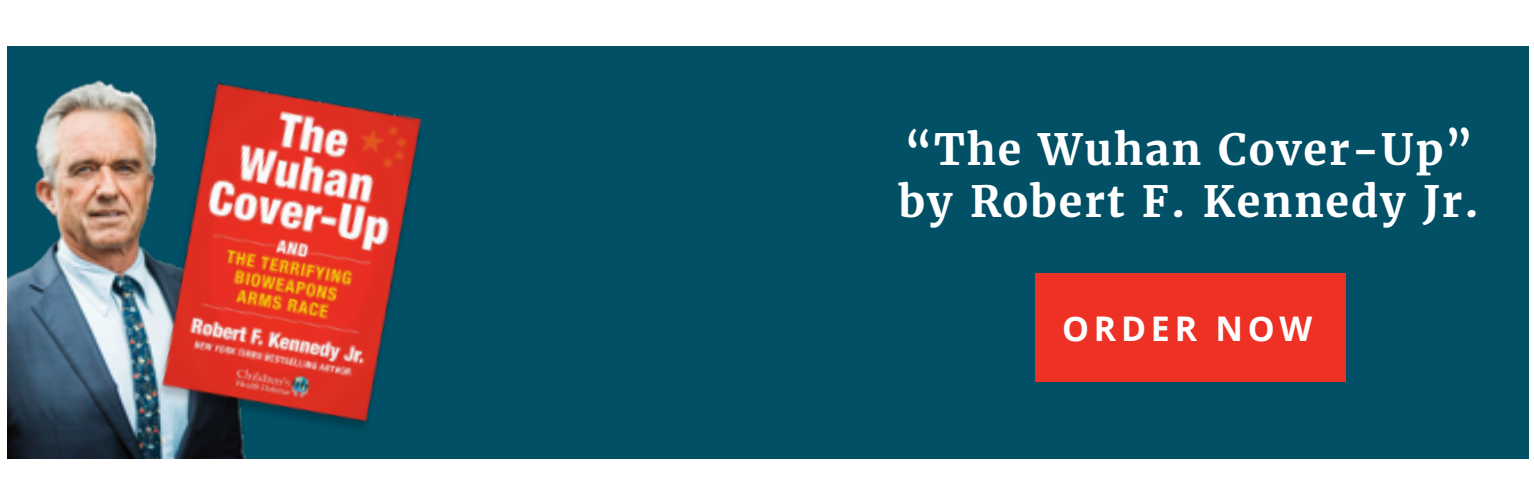
According to the NEJM article, GSK was unable to identify a mechanism by which the vaccine caused the preterm births. However, the company also couldn't identify any causes other than the vaccine being investigated.

Although GSK ended its trials due to the preterm birth safety signal, the U.S. Food and Drug Administration (FDA) in 2023 approved Pfizer's RSV vaccine for pregnant women, — even though Pfizer also reported elevated rates of preterm birth among vaccinated women during clinical trials for the vaccine, Abrysvo.

Pfizer said the rates of preterm birth during the Abrysvo trials were not statistically significant. However, the FDA limited approval of the vaccine for women in weeks 32-36 of their pregnancy.

The authors of an editorial that accompanied the NEJM article noted that although Pfizer's FDA-approved maternal RSV vaccine is bivalent and GSK's RSVPreF3-Mat is monovalent, "the vaccines are otherwise similar."

They also argued that RSV "poses a substantial burden" to infant health and that in considering maternal vaccination, risks and benefits had to be carefully weighed.


"The Wuhan Cover-Up" by Robert F. Kennedy Jr.
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Dr. David Healy, a drug safety expert, told The Defender he didn't think most people were aware of how serious premature birth is for both infants and mothers.

Healy said:

> "It leads to having a shorter lifespan, hypertension, ischemic heart disease, types 1 and 2 diabetes, lipid disorders and chronic kidney disease. Any mother who does her research — and women who give birth do more research than any other group of people on the planet — is going to find this out and be very worried."

Healy said in addition to the risks to the baby, "The vaccine also increases risks to the mother — there is an increased hypertension risk on [the GSK] and Pfizer's identical vaccine [Abrysvo]," he said.

"Increased hypertension in pregnancy, especially preeclampsia, has long-term health consequences for the mother — rather like the preterm birth issues for her infant," Healy added.

RSV is a common respiratory virus that usually causes mild cold-like symptoms but in rare cases can lead to hospitalization and death in infants and the elderly. By the age of 2, 97% of all babies have been infected with the RSV virus, which confers partial immunity, making any subsequent episodes less severe.

Midwife and nurse practitioner Mary Lou Singleton told The Defender:

> "As a mother and a pediatric primary care provider, I have had many frightening experiences with RSV. Every few years the virus moves through the children of my town, and in these bad RSV years at least a few of the infants and young children in my practice are hospitalized with severe cases of RSV. I am not cavalier about RSV.
>
> "Prematurity carries greater short and long term risks to children than RSV."

Singleton said that being born between 32 and 36.5 weeks gestation has lifelong negative effects. These babies are significantly more likely to die in the first year of life from all-cause mortality — "including RSV, for which they will only be partially protected according to the results of the study on the vaccine," she said.

Preterm babies also are more likely to have learning disabilities and behavioral disorders, which affect not only their quality of life but also the lives of their family members and the lives of everyone who interacts with them, Singleton said.

"As they age, they are more likely to develop heart disease, diabetes and high blood pressure than people who were born at term."

RFK Jr. and Brian Hooker's *New* Book: "Vax-Unvax"
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Risk of preterm birth in GSK trials 37% higher among vaccinated mothers

GSK launched a Phase 3 clinical trial in November 2020 to test the safety and efficacy of its vaccine against lower respiratory tract disease associated with RSV in infants born to women who had received the vaccine during pregnancy.

The company initially planned to enroll 10,000 pregnant women in the trials. However, after enrolling only 5,328 women and 5,233 infants by February 2022, the company stopped the trials because monitors detected an increase in preterm births.

In the study overall, researchers reported that 6.8% of infants among the vaccinated women were born preterm, as compared with 4.9% of those in the placebo group.

In other words, for every 54 infants born to women who received the vaccine, one additional preterm birth occurred.

The trial was conducted at sites in 24 countries on six continents, with approximately 50% of women located in middle- and low-income countries, where 97% of RSV-attributable deaths occur.

Researchers randomly assigned mothers in a 2:1 ratio to receive either the vaccine or a placebo between 24-34 weeks of gestation. They then tracked 3,426 infants whose mothers received the vaccine and 1,711 infants whose mothers received the placebo until they were 6 months old.

In February 2022, an independent data monitoring committee reported to GSK that at that time it identified there were 7.6% of preterm births in the vaccinated group were born preterm versus 5% in the placebo group.

The "imbalance" identified between the two groups continued after all mothers had delivered their babies. By the end of the trial, 237 of the 3,494 infants in the vaccine group (6.8%) were born before 37 weeks, compared with 86 of 1,739 (4.9%) in the placebo group.

That translated into a 37% increased risk of preterm births among vaccinated women.

Among the infants born prematurely, very preterm births (between 28 and 32 weeks) or extremely preterm births (before 28 weeks) occurred in 5.5% of the vaccine group and 2.3% in the placebo group.

Neonatal deaths also were higher in the vaccine group, occurring in 0.4% of the infants in the vaccine group (13 of 3,494) and 0.2% in the placebo group (3 of 1,739), which they also noted was not statistically significant.

"The use of statistical significance here to discount the existence of a problem is statistically illiterate. There is a very clear increase in risk that should not be discounted in this manner," Healy said.

He added:

> "In the GSK trial, 1 in 54 vaccinated babies were likely to have a preterm birth compared with not being vaccinated and even in these small trials there were neonatal deaths linked to the vaccine.
>
> "In contrast, there were no deaths linked to RSV. And we don't have any indications that getting RSV as an infant has long-term health consequences — any problems there are more likely linked to another underlying condition the child had prior to the RSV.
>
> "There might be a link to asthma but even this is dubious. The key point is 166 children have to be vaccinated to prevent one severe RSV infection.
>
> "Let me put it like this — forget the 69% efficacy this vaccine has only 0.5% efficacy in absolute terms."

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Another 'risky gamble' with the health of pregnant women?

The editorial commentary accompanying the NEJM article was written by Dr. Sonja A. Rasmussen and Dr. Denise J. Jamieson, who was named earlier this month to the CDC's vaccine advisory committee and was a key spokesperson promoting the COVID-19 vaccines as "safe and effective" for pregnant women.

Noting the researchers in the GSK trial could not identify the mechanism of increased risk of preterm births, Rasmussen and Jamieson walked through a series of potential explanations unrelated to the vaccine itself that could cause the higher rates of preterm births in the vaccine arm of the study.

Preterm births primarily occurred in low- and middle-income countries, they wrote. The study was carried out during COVID-19, and ultrasounds during the first trimester to determine fetal age were not done in nearly half the cases.

However, they then also conceded that there was no relationship to COVID-19 infections identified and misclassification of gestational age would have occurred at the same rate in both groups.

They concluded that "whether the safety signal in the RSVPreF3-Mat trial is real or occurred by chance is unknown." Still, they conceded that the results were concerning enough to warrant postmarketing surveillance of the bivalent vaccine — which is Abrysvo, currently approved and marketed by Pfizer.

They suggested that even if there does turn out to be a link between the bivalent (Pfizer's) vaccine and preterm births, "it is essential to weigh this small risk against the proven benefits of maternal RSV vaccination."

Healy came to a different conclusion, noting that "Based on the Novovax trial, this trial and the Pfizer trial I think any woman who has an RSV vaccine is making a big mistake and has been badly advised."

"But," he said, "I think a lot of American women understand this and most are in no rush to get it."

Singleton said it "would be great if we had a safe and effective way to prevent RSV from ravaging our communities every three to five years. But we don't."

Instead, she said, "We have another risky gamble with the health of pregnant women and infants that will further enrich Big Pharma and increase the already abysmally high rate of preterm birth in the United States."

She said a large percentage of children who get RSV will need to be hospitalized, but "a very small percentage" of children with the virus will die.

Singleton added:

> "Even though RSV has me shaking in my boots every few years as I am arranging transport to the hospital for very sick children in my care, I cannot recommend that mothers risk taking this new injectable technology.
>
> "We have no idea the extent of the new problems we may be creating with this new drug, and so far the data shows the risks do not justify the perceived benefit."

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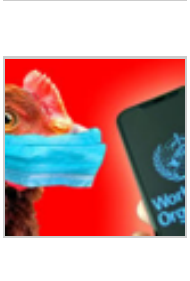
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Brenda Baletti, Ph.D.
Brenda Baletti, Ph.D., is a senior reporter for The Defender. She wrote and taught about capitalism and politics for 10 years in the writing program at Duke University. She holds a Ph.D. in human geography from the University of North Carolina at Chapel Hill and a master's from the University of Texas at Austin.

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BarbaraCharis
a month ago
Injections are contrary to nature. Humans are given 5 layers of skin to protect the bloodstream from contamination. A needle rapidly penetrates these 5 layers and injects contamininants into the bloodstream which don't belong.
Man-created matter should not be injected into the bloodstream, which will cause the natural immune system to work overtime trying to eliminatte it. The Vaccine Manufacturers lied, when they said their profit-making deadly products would strengten the Immune System. Our Medical Industry went along, because it would make them money...and our government was in the same place.
6 0 Reply

> **Leslie Taylor** → BarbaraCharis
> a month ago edited
> From RFK Jr's video (a/o 8 days ago) "How I See the State of our Nation" [see link below]
> This is a list of some of the the dramatic downturns in our nation's health, prosperity and freedom. Though these statistics mentioned in the video are indeed troubling, the entirety of his message is quite hopeful and inspiring.
>
> – Out of the richest countries in the world the U.S. is 35th in child poverty rates just above Mexico.
> – We rank 35th in literacy and 45th in press freedom.
> – We have one of the highest cancer rates in the world and our life expectancy now rates 59th according to the World Bank right behind Algeria.
> – Among the richest nations we now have the highest mortality rates, the highest gun deaths per capita and the highest number of teen pregnancies.
> – We lead the world in chronic disease and obesity.
> – According to the CDC 60% of Americans have chronic conditions. When his uncle was president only 6% of Americans had chronic disease.
> – Four in ten young people have depression and half of them have considered suicide. One in ten has anxiety, one in ten has ADHD and one in five is obese.
> see more
> 0 0 Reply
>
> **Ricky Ricardo** → BarbaraCharis
> a month ago
> Auto-immune diseases have skyrocketed since the ConVid BIOWEAPON injections began rolling out!
> 0 0 Reply

holisticpoet
a month ago
There are over 50 countries that rank higher in infant mortality than the U.S, yet all these countries spend less than the U.S. for prenatal care and somehow achieve better results. It does not take a rocket scientist to figure out that many of the interventions the U.S. ascribes to are actually harming these infants.
3 0 Reply

Ektor
a month ago
All vaccines, mRNA poisons and most drugs are critically risky. But they don't want you to know all the risks because that would cause people to perhaps think twice before blindly accepting all this poison crap.
2 0 Reply

> **Ricky Ricardo** → Ektor
> a month ago
> Sadly, today; many people seem to have great difficulty thinking even once!
> 1 0 Reply

WelcomeTheEagle88
a month ago
Word on the street is that RSV is poison manufactured via pertussis vaccination. Some of the earliest iterations in VAERS of RSV, physicians speculated an association to DPT vaxx
2 0 Reply

Gary Brown
a month ago
March 14, 2024 Study details why phase 3 trial of GSK's RSV vaccine for pregnant women was halted early

A study today in the New England Journal of Medicine discusses a phase 3 randomized, controlled trial of GSK's respiratory syncytial virus (RSV) vaccine in pregnant women that was stopped early owing to an increased risk of preterm birth.

https://www.cidrap.umn.edu/...
see more
2 0 Reply

Leslie Taylor
a month ago edited
I hope readers will consider this, it may very well be at the core of all the harm being inflicted on humanity largely by big pharma. I believe it was President George W. Bush who publicly stated that the next world war will be a war on minds.

I recently purchased an expensive appliance for my home that I was not considering nor did I want. I called the company that sold it to me as a result of an advertisement I received in the mail for the servicing of an existing appliance, an entirely different appliance than the one I purchased. The salesman and technician had engaging eyes (I always look people in the eye, perhaps not always a good idea) and he spoke in a melodic tone. After all was complete, and I out of three thousand dollars for something I didn't and still don't want, I thought perhaps I was hypnotized, tricked, into making the purchase. So I looked up hypnotic sales tactics and this is a well known practice and widely advertised (see links below to but a few of the many online). Many are aware of other ways hypnosis is likely being utilized to manipulate people, worst of all children and teenagers, especially with technology (with music, on TV, social media, youtube and spyphones) and perhaps also during face to face consultations with professionals. Perhaps they themselves, such as health care practitioners, are being hypnotized into pushing harmful and addictive pharmaceuticals, expensive and unnecessary diagnostic and surgical procedures onto their
see more
2 0 Reply

> **Ricky Ricardo** → Leslie Taylor
> a month ago
> One word: Marketing! Here's the father of "Ad Persuasion" who started it all:
> https://allthatsinteresting...
> 1 0 Reply
>
> > **Leslie Taylor** → Ricky Ricardo
> > a month ago edited
> > Ricky, Thank you for this interesting article about Edward Bernays (b. 1891 d. 1995 at 103), Sigmund Freud's nephew, and his successful career as a propagandist manipulating public opinion. He felt badly about his successful promotion of cigarette smoking for woman considered a low class thing for women to do at the time. Here are two of his quotes from his 1928 book "Propaganda":
> >
> > "The conscious and intelligent manipulation of the organized habits and opinions of the masses is an important element in democratic society,"
> >
> > "Those who manipulate this unseen mechanism of society constitute an invisible government which is the true ruling power of our country. We are governed, our minds are molded, our tastes are formed, our ideas suggested, largely by men we have never heard of."
> > 1 0 Reply
> >
> > > **Ricky Ricardo** → Leslie Taylor
> > > a month ago
> > > You're welcome, Leslie. There is a wealth of information available, on so many topics. Unfortunately, it's information that the majority of the population will never see. But...they can tell you the sports scores, the latest in fashion, what the latest "celebrity" gossip is, etc.. Sadly, they can't/won't talk about any topic of any importance.
> > > 0 0 Reply

Peter van der Stam
a month ago
Pfizer said the rates of preterm birth during the Abrysvo trials were not statistically significant.
Am I allowed to wonder who paid the FDA the most dollars??
And good on you GSK for retracting/ending the dangerous shots.
At last one positive point.
Thank you
1 0 Reply

r2bzjudge
a month ago
"Let me put it like this — forget the 69% efficacy this vaccine has only 0.5% efficacy in absolute terms."

I believe the regulation is that both the Relative Risk Reduction and the Absolute Risk Reduction are supposed to be told to the public. Obviously, they are hiding the latter. In absolute terms the Covid shots only had about 1% efficacy. The public only found out when they started getting Covid, after the Covid shot.

"They also argued that RSV "poses a substantial burden" to infant health..."

However, RSV "usually causes mild cold-like symptoms but in rare cases can lead to hospitalization and death in infants and the elderly." That doesn't sound like a substantial burden to infant health. The authors have a vested interest in ginning up the danger, in order to goose sales. A marketing gimmick. They won't be the one's suffering from a vaccine injury that the pharma company has no liability for.
0 0 Reply

r2bzjudge
a month ago
"Pfizer won approval of its nearly identical vaccine after the company
said the increased rate of preterm births in its trials was
statistically insignificant."

Pfizer said, isn't relevant to objective scientific data. As Dr. Malone said, they don't find what they don't look for. I presume the Pfizer trial data is not public, so there is no information available as to whether the trial was rigged in some way. Brook Jackson exposed rigging in the Covid injectable product trial. No reason not to suspect the same here.
0 0 Reply

Bill In Montgomey
a month ago
This would be a good story for a Defender journalist to highlight or follow-up on. A whistleblower has now come forward and says definitively that personnel at his hospital are finding those thick, white fibrous "clots" in "three to 10" patients EVERY WEEK.

In my opinion, this might be a narrative-changer if we get even more corroboration or a real investigation.

https://billricejr.substack...

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